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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,71Q	03/30/2000	Anders Dahlqvist	3377/99-Util	9098

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KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/19/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/537,710

Applicant(s)

DAHLQVIST ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 19, mailed on October 18, 2002), Applicants filed an election received on November 25, 2002 (Paper No. 20). Claims 1-23, 25, and 28-33 are pending in the instant Office action.

Election

2. Applicants' election with traverse of Group II, Claims 7-23, 28, and 29 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that searching for the DNA and the encoded protein does not present a serious search burden on the Examiner. This is not found persuasive because not only must these Groups be searched in separate class/subclass classifications, but also the commercial databases that must be searched are different – being either DNA or protein databases. These searches do not overlap and are not co-extensive. Applicants also argue that separate classification does not necessarily control division. The Examiner notes that the different groups were noted as distinct; the separate classification was noted to define the search burden should these distinct groups be searched together.

The requirement is still deemed proper.

3. Due to a reconsideration of the claimed subject matter, the following Office action is a supplemental restriction requirement that additionally requires the election of a species as noted below. Said supplemental requirement is at the discretion of the Examiner (see M.P.E.P. § 802 and 37 C.F.R. § 1.142) and is deemed appropriate and necessary in view of the complex subject

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matter of the instant claims and the extensive searching required to identify prior art relating to the instant subject matter.

Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-6, drawn to acyltransferase enzymes, classified in class 435, subclass 193.
 - II. Claims 7-23, 28, and 29, drawn to nucleotide sequences, vectors, and host cells, classified in class 435, subclass 252.3.
 - III. Claims 16, 17, 19-23, drawn to transgenic animals, classified in class 800, subclass 13.
 - IV. Claims 16-23, drawn to transgenic plants, classified in class 800, subclass 295.
 - V. Claim 25, drawn to triacylglycerols, classified in class 554, subclass 173.
 - VI. Claims 30-32, drawn to processes for producing triacylglycerol using particular nucleotide sequences and/or host cells, classified in class 435, subclass 159.
 - VII. Claim 33, drawn to processes for producing triacylglycerol using particular enzymes, classified in class 435, subclass 159.
5. The inventions are distinct, each from the other because of the following reasons:

The nucleotide sequences of Group II is related to the enzymes of Group I by virtue of the fact that the nucleotide sequences encode the enzymes. The nucleotide sequences have utility for the recombinant production of the enzyme in a host cell. Although the nucleotide

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sequences and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, the nucleotide sequences can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of Group I are related to the transgenic animals of Group III and the transgenic plants of Group IV by virtue of the DNA that encodes the enzymes and is the transgene in the organisms. These Groups are distinct for the reasons noted above between the nucleotide sequences and the enzymes. Thus, Group I is patentably distinct from Groups III and IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of Group I and the triacylglycerol of Group V are related because the enzymes can be used to produce the triacylglycerol. However, these products are wholly distinct having entirely distinct structures, functions, methods of production, etc. Thus, Groups I and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for

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examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of Group I are related to the methods of Group VI because the enzymes are encoded by DNA used in the methods. However, the enzymes themselves are neither used nor produced in the claims methods. Thus, Groups I and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

Groups I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the enzymes of Group I can be used in a materially different process of using that product, such as in the *in vivo* production of antibodies and/or in enzyme activity assays. Thus, Groups I and VII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The nucleotide sequences of Group II are related to the transgenic animals and plants of Groups III and IV, respectively, as combination and subcombination. Inventions in this

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relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the nucleotide sequence does not require the particulars of a transgenic plant or animal since it can be used in bacterial host cells. The subcombination has separate utility such as production of triacylglycerol in plants. Thus, Groups III and IV are patentably distinct from Group II. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The nucleotide sequences and transgenic organisms of Groups II-IV and the triacylglycerol of Group V are related because the nucleotide sequences encode the enzymes that can be used to produce the triacylglycerol. However, these products are wholly distinct having entirely distinct structures, functions, methods of production, etc. Thus, Groups II-IV are patentably distinct from Group V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleotide sequences of Group I can be used in a materially different process of using that product, such as in the *in vitro* production of the encoded enzyme. Thus, Groups II and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The nucleotide sequences of Group II are related to the methods of Group VII because the enzymes are encoded by DNA are used in the methods. However, the nucleotide sequences themselves are neither used nor produced in the claims methods. Thus, Groups II and VII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The transgenic plants of Group III and the transgenic animals of Group IV are related by virtue of having the same transgene in the organisms. However, these Groups are distinct by virtue of their wholly different structures and functions. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

Groups III and IV are related to Groups VI and VII as the relationship of Groups II with Groups VI and VII is noted above. They are distinct for the same reasons noted above and would require an unduly burdensome search for the reasons noted above.

Election of Species

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) For Groups I and VII (amino acid sequences), species are SEQ ID NOs: 2, 6, 8, 13-18, 20, 22, and 27.
- b) For Groups II-VI (DNA sequences), species are SEQ ID NOs: 1, 3-5, 7, 9-12, 19, 21, 23-26, and 28-31 (the election of any one SEQ ID NO will receive a search according to related the DNA sequence and any DNA encoding the *associated* amino acid sequence).

The Examiner notes that SEQ ID NO:25 is in Claim 5 as an amino acid, but is a DNA sequence in the listing provided on July 22, 2002 and is included above in the species of DNA sequences above.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, in Group I, Claims 1 and 3 are generic; in Group VII, Claim 33 is generic. In Group II, Claims 7, 8, 12-23, 28, and 29 are generic; in Groups III-VI, all the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Notice of Possible Rejoinder

7. The Examiner notes that if product claims are found to be allowable, then process claims, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Claims in Group VI are methods of using Claims in Group II and Claims in Group VII are methods of using Claims in Group I. Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

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Election

8. A telephone call was made to Daniel Kim on February 10, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

9. A complete response to the instant Office action must include an election of invention (Group) to be examined and an election of species to which the claims may be limited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

February 10, 2003

